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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/797,958

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Stephen Brushey

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05/08/2009

JONES DAY
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NEW YORK, NY 10017

EXAMINER

BOUCHELLE, LAURA A

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

05/08/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/797,958	Applicant(s) BRUSHEY, STEPHEN	
	Examiner LAURA A. BOUCHELLE	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 102

Claim Rejections - 35 USC § 103

1. Claims 1, 4, 6-8, 11, 16 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hafer et al (US 7386341). Hafer discloses a catheter system comprising a flexible cylindrical tube 56 terminating in an open distal tip and having a plurality of openings 162, a conductive cap 150 closing the open distal tip of the tube, a flexible conductive member 57 attached at one end to the conductive cap and running the length of the tube (Col. 12, lines 8-22, 54-56). See Figs. 10A-C. As shown in Fig. 10C, the tube has at least 4 openings 162 that are off set from each other at least 180 degrees and arranged in at least 2 rows. The tube is formed of a sterilizable thermoplastic material (col. 6, lines 36-37).
2. The end cap 150, called a “slug” by Hafer, may be interpreted as being dome shaped. Alternatively, it would have been obvious to form the slug in the same shape as the conductive tip 72 shown in fig. 3 of Hafer for example. The Federal Circuit has found that it is obvious to combine embodiments in a single prior art reference stating, “Combining two embodiments disclosed adjacent to each other in a prior art patent does not require a leap of inventiveness.” (Boston Scientific v. Cordis, Fed. Cir. 2009). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the embodiments to modify the end cap shown in Fig. 10 to have a dome shape as shown in fig. 3 since the combination is a predictable variation.

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3. Claims 2, 3, 5, 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hafer in view of Massengale (US 2002/0052576). Claims 2, 3, 5, 9 call for dimensions of the device. Hafer is silent as to the dimensions, only disclosing that the tube is small enough to be inserted through a needle. Massengale discloses a fluid delivery catheter comprising a catheter having a distal tip comprising an end cap 348, and a plurality of openings 364, 372, 356, 404. The catheter has an inner diameter of 0.019 inches, and an outer diameter of 20 gauge (Page 12, paragraph 0133). The length of the diffusion area may be any desired length (page 12, paragraph 0137), but is preferably about 0.5 inches to 20 inches (page 13, paragraph 0140). The adjacent openings may be spaced between 0.125 inches and 0.25 inches (page 13, paragraph 0140). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Hafer to have the dimensions as taught by Massengale because both devices are used to deliver fluids to the body and so the device of Hafer would perform equally well with the dimensions of Massengale.

4. Claim 10, 12, 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over in view of Beisel (US 5947940). Claim 10 differs from the teachings above in calling for a window for visualizing flashback. Beisel teaches an epidural catheter similar to that of Hafer but further including a window for visualizing flashback (Col. 3, lines 40-42). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Hafer to include a flashback window as taught by Beisel to assist the user in proper placement of the device.

5. Hafer is similarly silent as to the specific material of the tube. Massengale discloses that the catheter may be formed of a sterilizable plastic such as polyamide (page 12, paragraph 0133). It would have been obvious to one of ordinary skill in the art at the time of invention to form the

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tube of Hafer from the claimed materials as taught by Massengale because it is known to use such materials in medical devices for their biocompatibility, non-reactiveness, and ability to be sterilized.

6. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hafer in view of Massengale as applied to claim 11 above, and further in view of Brushey (US 6676643). Claim 14 differs from the teachings above in calling for the device to be formed of polyurethane and at least one siloxane. Brushey teaches that a device may be formed of polyurethane and at least one siloxane. Siloxane, commonly called silicone rubber, is well known in the medical arts for its flexibility and biocompatibility. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to form the device of Hafer in view of Massengale of polyurethane and siloxane as taught by Brushey because both materials are commonly used for their flexibility and biocompatibility.

7. Claims 15, 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hafer. Regarding claim 15, Hafer is silent as to the specific material of the conductive material. Hafer discloses that the flexible element and the end cap are formed of a conductive metal. It is well known in the art to use stainless steel in electrical stimulation devices because it is biocompatible and nonreactive. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to form the conductive flexible element from stainless steel.

8. Regarding claim 17, Hafer fails to disclose the dimensions of the wire. Where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform

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differently than the prior art device, the claimed device was not patentably distinct from the prior art device. See MPEP 2144.04.

Response to Arguments

9. Applicant's arguments filed 1/14/09 have been fully considered but they are not persuasive. Applicant argues that Hafer discloses all of the components of the recited claims in different embodiments, and that making a combination of these components drawn from different disclosed embodiments would not be obvious to one of ordinary skill in the art because Hafer, presumably one of skill in the art did not make the combination. The Federal Circuit has very recently handed down a decision that argues the opposite. The Federal Circuit found that combining two embodiments disclosed adjacent to each other in a prior art patent does not require a leap of inventiveness. (*Boston Scientific v. Cordis* (Fed Cir. 2009)). In the instant case, it would not take a leap of inventiveness to combine the dome shaped tip 72 shown in Fig. 7 with the slug 150 shown in Fig. 10A. Therefore, the fact that Hafer did not expressly disclose the combination does not render the combination non-obvious.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA A. BOUCHELLE whose telephone number is (571)272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Laura A Bouchelle
Examiner
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